IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

USING IREx AS THE STUDY MANAGER: A STEP-BY-STEP GUIDE

The **IREx Study Manager** is someone from the lead study team or coordinating center who is responsible for managing participating site access to IREx and overseeing participating site readiness for single IRB (sIRB) review. For more detailed information on how to use IREx, check out the Study Manager User Manual on the IREx Resources page here.

STEP 1 — SUBMIT THE LEAD SITE TO THE SIRB

- ❑ Discuss the submission process with the sIRB (e.g., What is needed for the lead site; How are participating sites submitted to the IRB for review?)
- ❑ Ask the sIRB if they have or want to use the IREx Reliance Instructions Template to communicate next steps to sites.

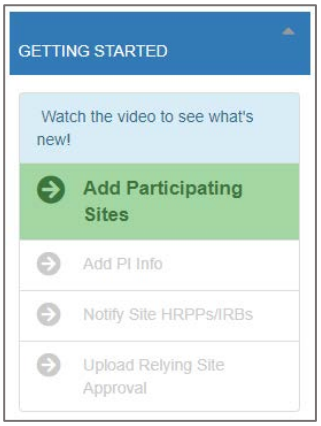
STEP 2 — THE STUDY IS CREATED IN IREX [COMPLETED BY THE SIRB]

You will receive access to IREx via an email notification.

STEP 3 — WORK WITH SITES WHO HAVE NOT COMPLETED ALL REQUIRED AGREEMENTS (IF APPLICABLE)

If any of your sites have not executed all of the required agreements, the sIRB may (1) reach out to the site HRPP about any missing agreements before you have approval for the overall study or (2) ask you to instruct the site investigator to contact their local HRPP about the missing agreements. Sites who have completed all agreements do not typically have any action items until the lead site has been approved.

STEP 4 — ADD SITES TO THE STUDY IN IREX



Use the GETTING STARTED Checklist to guide your steps in IREx. The first step is to **Add Participating Sites** to the study so you can track their agreement status.

- ❑ Add sites using their name (avoid abbreviations) or Federalwide Assurance # (FWA). You can also add sites that do not appear in the search.
- ❑ ***Combo Sites*:** If you know an investigator engages multiple FWAs, check the box, **This PI engages other sites** after entering their contact information. This will create a Combo Site showing a link icon before the sites' name on the Status Summary tab. Read more about Combo Sites here.
- ❑ A PI name and email address are required before the site can be notified of the study, but you can list the site name without the PI and retun later to enter it. Tip: We also recommend including a site coordinator name and email.

THESE STEPS OCCUR AFTER APPROVAL FOR THE LEAD SITE

STEP 5a — EMAIL APPROVED STUDY MATERIALS TO STUDY TEAMS (OUTSIDE OF IREX)

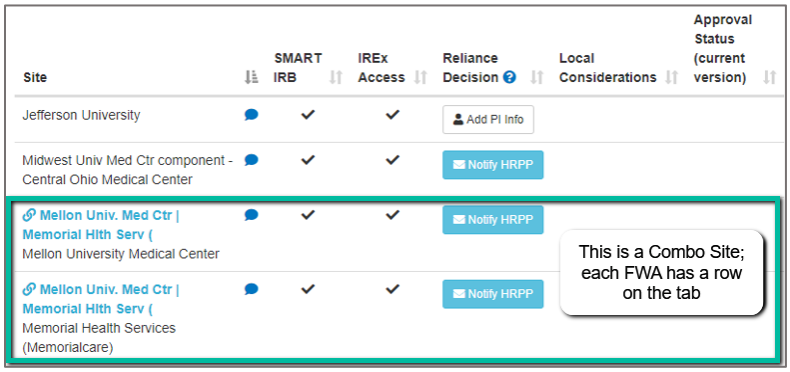
- ❑ Sites need the approved study materials to submit to their local HRPP, which is usually required before the HRPP can complete the information in IREx and grant their study teams access to IREx.
- ❑ Include the approved protocol and ICF templates; lead site IRB approval letter; reliance instructions; contracts; and other regulatory documents. You can also share this 4-minute IREx video tutorial.

STEP 5b

NOTIFY SITES OF THE STUDY IN IREX

After the lead site is approved and the approved study materials are sent to study teams:

- ❑ From the Status Summary tab, click **Notify HRPP** to alert site HRPPs of their access to the study in IREx. This sends an email to the HRPP and study team and prompts them to connect around their local reliance process. You, the site PI, and coordinator (if provided) are copied on the email.
- ❑ You can notify sites at different times, depending on when the site is being onboarded to the study. **Tip:** Only sites with IREx access can be notified. Non-IREx site's HRPP/IRB director or manager can join here.

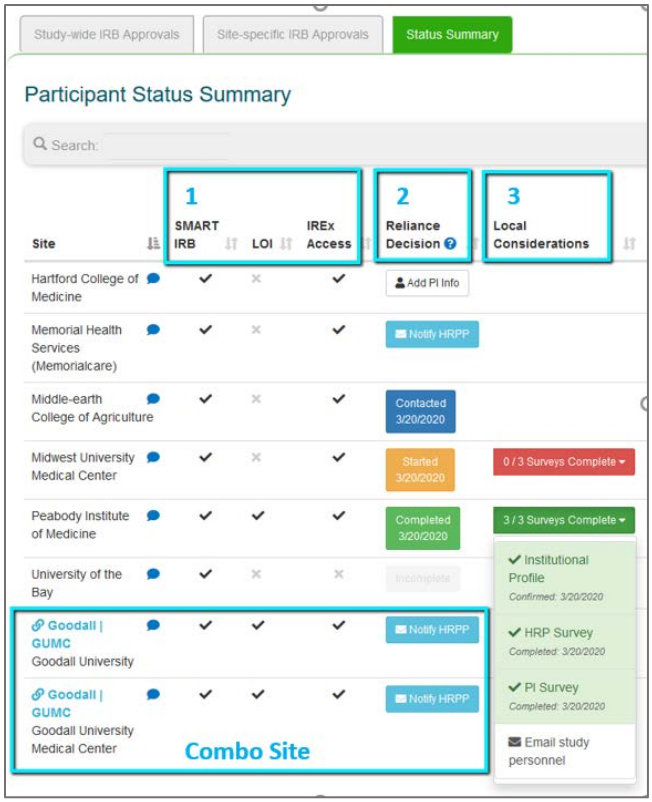


***Combo Sites*:** Be sure to notify all Combo Site FWAs at the same time.

STEP 6

TRACK SITE READINESS FOR SIRB REVIEW USING THE STATUS SUMMARY TAB

1. Is the site signed onto the required agreements?
   - SMART IRB agreement
   - LOI (column shown if applicable)
   - IREx Access (HRPP can join here)
2. Has the site's HRPP indicated reliance?
   - **Add PI Info** = add PI email & name
   - Notify HRPP = site has not been contacted yet and do not have access to the study
   - Contacted = date sent study notification
   - Started = date HRPP first accessed study
   - Completed = date HRPP indicated reliance
   - Incomplete = incomplete agreements
3. Are local considerations complete?
   - **Institutional Profile**: Completed by the HRPP and includes institutional-level information.
   - **HRP Survey:** Completed by the HRPP and includes applicable local requirements for this study.
   - **PI Survey:** Completed by the PI and validated by the local HRPP; includes information about conduct of the study.



Combo Sites have only one PI Survey. It can be viewed by any site in the Combo but is validated by the Primary HRPP. Local Considerations cannot be exported until documentation is complete for all sites in the Combo.

STEP 7

SITE TRACKING AND FOLLOW UP REGARDING OUTSTANDING ACTION ITEMS

Use the Status Summary tab to guide your follow up with sites.

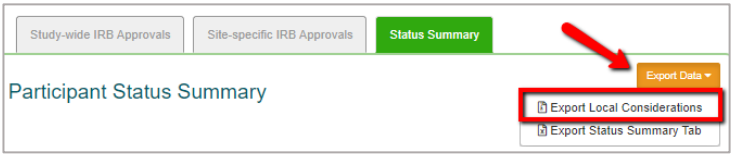
- ❑ **If any steps are incomplete,** ensure the study team has submitted to their local HRPP. If so, ask the study team to follow up with their HRPP Liaison (found here) regarding any additional information that is needed.
- ❑ **Incomplete PI Survey:** Send a reminder to the PI using the **Email study personnel** link in IREx.
- ❑ **Need to Add/ Remove Sites:** Edit the list of participating sites using the **Manage Project** button **> Edit Participating Sites**. **Tip:** Ensure newly added sites have reliance instructions, the approved study materials, and an introduction to using a single IRB.

STEP 8

EXPORT LOCAL CONSIDERATIONS (IF APPLICABLE)

You will receive an email from IREx when a Site completes local considerations. All sites in a *Combo Site* must complete their documentation before the email is sent.

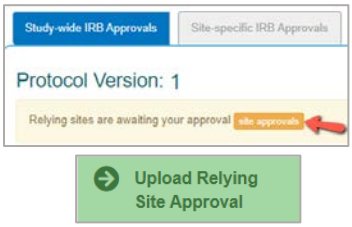
- ❑ Before exporting, pre-screen the surveys for completion by clicking on each survey in the Status Summary tab.
- ❑ Ensure consent forms are uploaded to the HRP Survey, if applicable, and that they are complete.
- ❑ **If changes or clarifications are needed, the HRPP liaison at the site can edit the PI survey and HRP survey. You may need to contact the local study team to work with their HRPP to make changes.**
- ❑ Once a site is ready to be submitted to the sIRB, from the Status Summary tab, click the **Export Data** button and select **Export Local Considerations**. Select the site(s) and save their files. Submit the site's files to the sIRB for review.

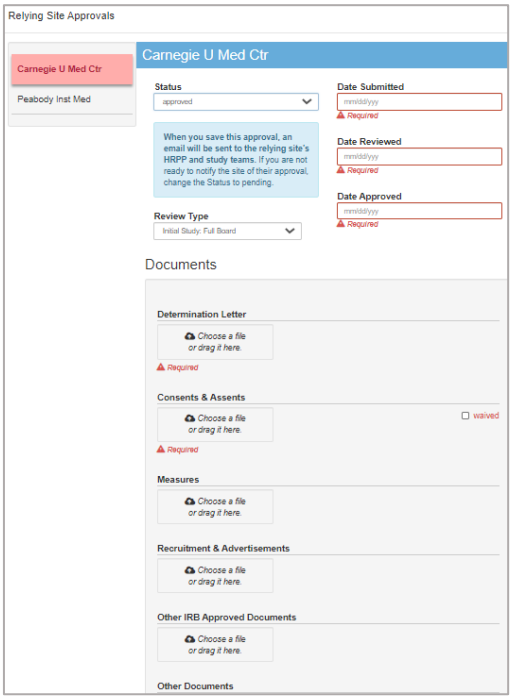


STEP 9

UPLOAD INITIAL SIRB APPROVALS FOR PARTICIPATING SITES (AS ISSUED BY THE SIRB)

To upload a Site Approval, click the **site approvals** button at the top of the Approvals tabs or click the **Uploading Relying Site Approvals** step on your GETTING STARTED checklist:





- ❑ Select the **site name** from the list on the left;
- ❑ Change the Status to **approved**;
- ❑ Indicate the **Review Type**;
- ❑ Enter the **Date Submitted, Reviewed,** and **Approved**; and
- ❑ Upload the site's **Determination Letter, Consents & Assents** (or waive), and other site specific IRB approved documents. *Combo Sites* will have one set of documents.

The Site HRPP and study team are notified by email when new approvals are uploaded, and you are cc'd.

STEP 10

UPLOAD OTHER APPROVALS FOR PARTICIPATING SITES

Study Managers can upload additional approvals, but please confirm the sIRB prefers you upload these:

1. Site Amendments: Upload site changes (e.g., PI change) from the Site-specific IRB Approvals tab using the **site amendment** button by the site name.

2. Continuing Reviews & Study-wide Amendments: Each has 3 steps:
   a. **Create the approval:** From the **Manage Version** menu, select the approval type and complete the information in the dialog.
   b. **Upload approval for lead site/Overall Study:** From your GETTING STARTED checklist, click **Upload Overall Study Approval**, after setting the status to approved, the required fields will be highlighted. Once completed, publish the approval for the lead site.
   c. **Upload approvals for Relying Sites:** This can be done from your GETTING STARTED checklist. After selecting a site and changing their **Status** to approved, the lead site's Determination Letter and dates will auto-fill. Be sure to delete any files that are no longer in use and upload updated / new documents.